Remarks

Claims 1-31 are pending and have been made subject to a restriction requirement. Claims 1, 22, and 24-31 are amended herein.

Explanation of the Amendments

The amendments to the specification are entered to correct minor typographical and clerical errors. The amendment at p. 32 line 24 corrects a typographical error where "mg/kg/day" instead of "mg/day" in describing suitable doses. The person skilled in the art would easily recognize the existence of the error since "mg/kg/day" would result in grossly excessive doses. For example in the recited range of 100 to 1500 mg/kg/day would require a dose in the range from about 7g to 105g for an average (70kg) human being. Such doses would be recognized as extremely high and clearly erroneous by the person skilled in the art. The person skilled in the art would also immediately recognize a reasonable dose range for human would be obtained that if the "per kg" notation were recognized as an error, and thus immediately recognize this as the appropriate correction.

Claim 1 is amended to make clear that the claims are directed to methods of lowering body temperature where an individual is in need of such treatment. The specification makes clear, both by setting forth numerous examples, and explicitly (see p. 11 lines 1-5) that the claimed method is directed to lowering body temperature where such lowering is therapeutically beneficial, i.e. where the temperature is abnormally high, or where lowering of basal body temperature is therapeutically beneficial.

Claim 22 is amended to be dependent from claim 1.

Claims 24-30 are amended to enhance clarity by making clear that the claims are intended to require administration of the drugs specified therein.

Claim 31 is amended to correct a spelling error.

Response to the Restriction Requirement

The examiner has required election between Groups I(a), I(b) and II, characterized by the examiner as:

> Group I(a) Claims 1-21, drawn to a method of lowering body temperature of an individual with a compound of Formula I.
>
> Group I(b). Claims 22-30, drawn to a method of lowering body temperature of an individual with a compound of the Formula I in combination with one or more additional therapeutic agents selected from the group consisting of estrogen agonists, progesterone agonists, selective estrogen receptor modulators, bisphosphonates, selective serotonin reuptake inhibitors, norephiephrine serotonin reuptake inhibitors and gamma aminobuteric acid modulators.
>
> Group II. Claim 31, drawn to a composition comprising a compound of the Formula I in combination with one or more additional therapeutic agents selected from the group consisting of estrogen agonists, progesterone agonists, selective estrogen receptor modulators, bisphosphonates, selective serotonin reuptake inhibitors, norephiephrine serotonin reuptake inhibitors and gamma aminobuteric acid modulators.

As between Groups I and II, **applicants elect Group I**. As between Groups I(a) and I(b), **applicants elect Group I(a)**. Applicants **traverse** the restriction requirement insofar as restriction has been required between Groups I(a) and I(b).

The traversal is in part on the grounds that claim 1 is a linking claim linking groups I(a) and I(b) since claims 2-30 all depend from claim 1. The inventions claimed in claims 2-21 and 22-30 all define species of the invention generically claimed in claim 1, therefore restriction as between Groups I(a) and I(b) is clearly not proper.

Further, restriction of Groups I(a) and I(b) is not proper because the groups overlap in scope. As MPEP 806.03 explains:

> "Where the claims of an application define the same essential characteristics of a *single* disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are not

directed to distinct inventions; rather they are different definitions of the same disclosed subject matter, varying in breadth or scope of definition."

An embodiment of the invention is a method where a compound of formula I is used in conjunction with estrogen antagonists for the treatment of hot flashes associated with menopause. See claim 23 in Group I(b). However, this embodiment of the invention is also encompassed by, for example, claim 14 in Group I(a) (directed to a method of lowering body temperature by administering a compound according to formula I to an individual suffering hot flashes during menopause). Since this single embodiment falls within both Groups, restriction is not proper under MPEP 806.03.

The traversal is also on the ground that the examiner has not shown a serious burden of examining both Groups of claims. The examiner stated in section 3 of the office action that the inventions would require a different field of search, although the examiner provided no reasons why examination of Groups I(a) and (b) would require a different field of search. The examiner has not, for example, provided any different classification of the groups to show that the Groups would be differently classified, or how the field of search would be different. It appears to the applicants that a search of the full scope claim 1 would encompass a search the subject matter of claims 22-30 given that claims 22-30 incorporate all the limitations of, claim 1. Therefore, there is no additional burden of searching Group I(b) when Group I(a) is searched.

Applicants also traverse the election of species requirement. In making the election of species requirement, it is respectfully submitted that the examiner has failed to follow the requirements for an election of species requirement to be proper as set forth in MPEP 809.02(a). Specifically:

(1) The examiner failed to identify a generic claim (or otherwise to indicate that no generic claim was present) (see MPEP 809.02(a)(A));

(2) The examiner failed to identify each of the disclosed species among which the claims were to be restricted, or alternatively to group claims in accordance with the species into which they were to be restricted; nor has the examiner alleged, or provided reasons why,

the species among which election was required were supposed to be independent or distinct (see MPEP 809.02(a)(B)).

As a result of the examiner's failure to follow the correct procedure for requiring an election of species, it is not clear to the applicants the species among which election is being required. However, in a good faith effort to provide a full response, applicants interpret the election of species, as being requirements to make elections as follows:

(i) identifying a particular compound according to formula I used in the method of lowering body temperature to facilitate the examiner's search of claim 1, which is generic as to the compounds of formula I used in the method;

(ii) identifying a disorder associated with an elevated body temperature to facilitate the examiner's search of claim 9, which is generic as to the disorder associated with elevated body temperature;

(iii) to identify an additional therapeutic agent used together with the agent of formula I in the method of lowering body temperature to facilitate the examiner's search of claim 22, which is generic as to the at least one additional compound in addition to the compound of formula I used in the method of claim 22.

It is the applicants understanding therefore, that the election of species requirement constitutes three separate elections rather than a single election.

With this understanding, the applicants make elections as follows:

(i) a particular compound according to formula I used in the method of lowering body temperature in claim 1: (S)-1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7,8-dimethoxy-5H-2,3-benzodiazepine (i.e. (S)-tofisopam);

(ii) a disorder associated with an elevated body temperature in claim 9: hot flashes associated with menopause;

(iii) an additional therapeutic agent used together with the agent of formula I in the method of lowering body temperature in claim 22: estrogen agonists (or estradiol if identification of a specific compound is required).

The claims readable on the species elected by the applicants are as follows:

(i) methods of lowering body temperature by administering (S)-1-(3,4-dimethoxyphenyl)-4-methyl-5-ethyl-7,8-dimethoxy-5H-2,3-benzodiazepine: claims 1, 2, 7-8, 9-21 (for particular disorders), and 22-30 (in combination with another drug);

(ii) a method of lowering body temperature where a compound of formula I is administered to an individual suffering hot flashes associated with menopause: claims 1-9, 13-15, and 22-30 (if a second compound is administered).

(iii) a method of lowering body temperature where a compound of formula I is administered to an individual in conjunction with an estrogen agonist (or estradiol) for treating hot flashes associated with menopause: claims 1-22, 23 (in combination with a progesterone agonist) and 24 (if the estrogen agonist is estradiol).

If applicants have misinterpreted the examiner's election of species requirement in making the above elections, the examiner is respectfully requested to set forth the election of species requirement clearly identifying the particular independent or distinct species that are alleged to be present, and among which election is required. Applicants reserve the right to respond further should the examiner supplement the restriction or election of species requirements.

Respectfully submitted,

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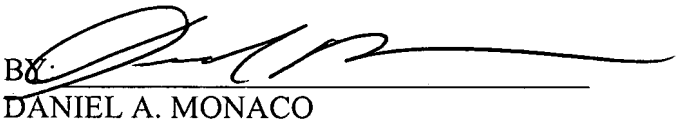

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